



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 16, 2023

Brian Hogan
Agent, KRK Consulting LLC
MicroSafe Group DMCC
Liwa Heights, 3908
Jumeirah Lake Towers, Dubai, UAE
Electronic Transmittal: [brianhogan330@gmail.com]

Subject: PRIA Label Amendment – Add Efficacy, Label Claims and Revised EVP
Product Name: Nanocyn
EPA Registration Number: 100798-1
Received Date: August 15, 2022
Action Case Number: 00385458

Dear Brian Hogan:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6), you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Wanda Henson by phone at (202) 566-0650, or via email at henson.wanda@epa.gov.

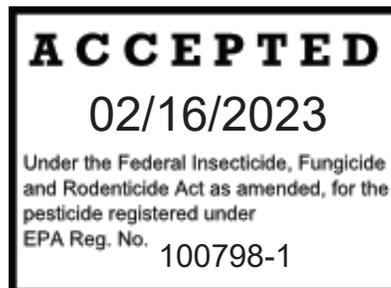
Sincerely,

A handwritten signature in black ink, appearing to read 'D Fuller', with a long horizontal line extending to the right.

Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

Text that appears in {braces} are notes to reviewer. Text that appears in [brackets] is optional. Text that appears in (parenthesis) are required clarifiers or acronyms. X is a placeholder for any number.



Nanocyn®

[Alternate Brand Names: Nanocyn Disinfectant, Nanocyn Hospital Disinfectant, Nanocyn Broad Spectrum Disinfectant]

[Hospital] [healthcare] disinfectant for hard non-porous surfaces

ACTIVE INGREDIENT:

Hypochlorous Acid: 0.026%

OTHER INGREDIENTS: 99.974%

[Water]

TOTAL: 100.000%

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS: X [L] [mL] [gal] [oz] [fl oz]

EPA Reg. No. 100798-1

EPA Est No. 101961-MEX-1

MANUFACTURED FOR:

MicroSafe Group DMCC

Liwa Heights, 3908

Jumeirah Lake Towers, Dubai

United Arab Emirates

Manufactured by Oculus Technologies of Mexico, a subsidiary of Sonoma Pharmaceuticals

PRECAUTIONARY STATEMENTS

Physical or Chemical Hazards: [This product] [Nanocyn®] is an oxidizer. Do not use with or store near any reducing agents. Do not mix with other chemicals.

MARKETING CLAIMS {These can appear anywhere on the label}:

[This product] [Nanocyn®] is a disinfectant solution for use on hard non-porous [inanimate] surfaces.

[This product] [Nanocyn®] is a super-oxidized, pH-neutral, water-based [Hospital] [healthcare] disinfectant for hard for non-porous surfaces.

[This product] [Nanocyn®] is a ready-to-use product that is especially useful in hospitals, patient care areas, and dental offices.

When used according to the direction for use, [this product] [Nanocyn®] disinfects hard non-porous surfaces including: stainless steel, chrome, glass, vinyl, glazed porcelain, non-porous plastics, baked enamel and glazed tile in the below application areas.

<ul style="list-style-type: none">• [Cleans] [and] [or] [kills] [disinfects] [removes] [attacks] [gets rid of 99.9% of] bacteria• [Cleans] [and] [or] [kills] [disinfects] [removes] [attacks] [gets rid of 99.9% of] viruses**• [Cleans] [and] [or] [kills] [disinfects] [removes] [attacks] [gets rid of 99.9% of] fungi• Deodorizes by disinfecting• Designed for healthcare• Disinfecting formula• Disinfection technology• Disinfects odor causing bacteria	<ul style="list-style-type: none">• For healthcare use• For hospital use• Formulated –or- super-oxidized water-based disinfectant• Formulated with patented hypochlorousacid technology• Helps reduce cross contamination on treated hard, non-porous surfaces• Hospital disinfectant• Oxidizing agent to provide disinfection
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<ul style="list-style-type: none"> • [Antimicrobial] [and] [or] [antibacterial] [virucidal**] • [Bacteria] [and] [or] [viruses**] • [Bactericide] [Bactericidal] • [Fungicide] [Fungicidal] • [Hospital] [Healthcare] disinfectant • Can help reduce the risk of cross-contamination on treated, non-porous surfaces. • Cleans and disinfects treated hard non-porous surfaces • [Clean] [and] [or] [disinfect] on the go 	<ul style="list-style-type: none"> • Effective against the tough non-enveloped Norovirus • [Effective against] [Kills] Bacteria • [Effective against] [Kills] Viruses** • [Effective against] [Kills] Fungi • [Effective against] [Kills] Germs • For hospital [&] [veterinary] hard nonporous surfaces
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<ul style="list-style-type: none"> • Water based, Proven disinfection technology • Powered by Microcyn® technology • Ready to use disinfectant • Ready to use formula • Real world contact times on pathogens* • Super-oxidized water works by oxidizing microorganisms for broad spectrum disinfection • Tough on germs, easy on hard, non-porous surfaces • [Effective against] {insert organism from table} [in {insert contact time from table}] • Broad Spectrum Disinfectant • Kills 99.9% of germs 	<ul style="list-style-type: none"> • Virus** [antiviral] disinfectant • Virucide** • Tough on germs around patient areas on hard non-porous surfaces • Tough on germs for everyday use on hard non-porous surfaces • Use on hard non-porous surfaces that you are concerned about [bacteria] [and] [or] [viruses**] • Use on hard, non-porous surfaces where hazards of cross-contamination between treated surfaces is of primary importance at different sites • disinfects on hard non-porous healthcare surfaces • [Virucide**] [Virucidal**] • When used according to the directions for use, this product disinfects hard non-porous surfaces including in a healthcare environment
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<ul style="list-style-type: none"> • No rinsing • Non-abrasive • Non-corrosive • Non-flammable • Packaging made with [x%] recycled -or-recyclable plastic • Ready to use • [The] Smell of clean • Cleans, Deodorizes and Disinfects hard, nonporous surfaces • Great for (cleaning and) disinfecting hard, non-porous surfaces on (ships) (liners) • Kills Norovirus in 30 seconds. • (Clean) (Disinfect) hard, non-porous surfaces in (guest)(cabin(s)) (rooms) (areas) • Daily (Everyday) hard, non-porous Surface Cleaner (&) (Disinfectant) (for) cruise (ships) (liners) • (Great) For (cleaning) (disinfecting) hard, non-porous surfaces in (cabin(s)) (guest) (rooms) (areas) • (disinfecting) (food service) (dining) areas • For (disinfecting) cruise (food service) (sports) (bars) (lounges) (pubs) • For (cleaning) (disinfecting) hard, non-porous surfaces in/on (technology) for cruise ships 	<ul style="list-style-type: none"> • No fragrance added • No [smell] [odor] [and] [or] [buildup] [residue] • No [mixing] [diluting] [required] • [Non-corrosive] [non-staining] [of surfaces] • No special handling or disposal requirements • No Personal Protective Equipment (PPE) required • (Great) for (cleaning) (disinfecting) hard, non-porous surfaces in/on agricultural (equipment) (machinery) • (Great) for (cleaning) (disinfecting) hard, non-porous surfaces in (poultry) (and) (cattle) (areas) (housing) • (Great) for (cleaning) (disinfecting) hard, non-porous surfaces in (Equine) (areas) (housing) • For (cleaning) (disinfecting) hard, non-porous surfaces in/on (technology) for agriculture (poultry) (cattle) • Great for cleaning hard, non-porous yoga (mats) (gear) (rooms) • For (cruise) hard, non-porous surfaces in/on workout (gyms) (equipment) (machines) • (Great) for hard, non-porous surfaces in/on children's (play) (workout) (gear) (equipment)
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<ul style="list-style-type: none"> • Kills (Germs) (Bacteria) (& (Viruses*) hard, non-porous surfaces in (cruise) (marine) (vessel(s)) (ship(s)) (bathroom(s)) • (Great) For (children's) (arcade) (laser tag) (cleaning) (disinfecting) • (Great) For (disinfecting)(cleaning) (VR) (virtual reality) (headsets) (equipment) • Cruise Ship (Airline) (Train) (Rail) food processing (preparation) areas 	<ul style="list-style-type: none"> • (Great) For (cleaning) (disinfecting) hard, non-porous surfaces in cruise (ship) (lounge(s)) (sitting areas) • (Great) for (cleaning) (disinfecting) food prep areas and food storage rooms • (Great) for hard, non-porous surfaces in kitchens. • (Great) for hard, non-porous surfaces in Medical/Sick Bays • (Great) for hard, non-porous surfaces in patient treatment rooms/areas
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EMERGING VIRAL PATHOGENS CLAIMS

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This Product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses
- Small Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...follow the directions for use for the following organisms on the label:
Enveloped Virus	Poliovirus type 1
Large, non-enveloped virus	Poliovirus type 1
Small, non-enveloped virus	Norovirus and Poliovirus type 1 (1 Minute)

Nanocyn has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, nonporous surfaces. Therefore, Nanocyn can be used against [name of emerging virus] when used in accordance with the directions for use against Poliovirus type 1 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. Nanocyn kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Poliovirus type 1 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labelling.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

To Disinfect Hard, Non-Porous Surfaces:

All surfaces must be pre-cleaned/cleaned before disinfection. Apply [this product] [Nanocyn®] with a cloth, wipe, mop, sponge, or (coarse) trigger spray. Allow to remain visibly wet for 8 minutes for bacteria, 1 minute for viruses** and 5 minutes for fungi. Allow surfaces to air dry. No rinsing required.

To Disinfect Hard, Non-Porous Surfaces, Specifically Against Methicillin Resistant Staphylococcus aureus – MRSA [and] [or] Trichophyton

interdigitate: All surfaces must be pre-cleaned/cleaned before disinfection. Apply [this product] [Nanocyn®] with a cloth, wipe, mop, sponge, or (coarse) trigger spray. Allow to remain visibly wet for 5 minutes. Allow surfaces to air dry. No rinsing required.

To Disinfect Hard, Non-Porous Surfaces, Specifically Against Norovirus

All surfaces must be pre-cleaned/cleaned before disinfection. Apply [this product] [Nanocyn®] with a cloth, wipe, mop, sponge, or (coarse) trigger spray. Allow to remain visibly wet for 30 seconds. Allow surfaces to air dry. No rinsing required.

To Disinfect Sensitive [Electronic] Equipment, Hard, Non-Porous Surfaces:

Pre-clean surfaces before disinfection. Apply [this product] [Nanocyn®] with a cloth or (coarse) trigger spray so that only enough solution is applied to keep the surface visibly wet for 10 min[utes]. Avoid over soaking and pooling [or puddling] of the solution. No rinsing is required. Allow surfaces to air dry.

*** ORGANISM LIST**

Bacteria		
Pathogen	Strain	Contact Time
Staphylococcus aureus	ATCC 6538	8 Minutes
Pseudomonas aeruginosa	ATCC 15442	8 Minutes
Salmonella enterica	ATCC 10708	8 Minutes
Methicillin Resistant Staphylococcus aureus - MRSA	ATCC 33592	5 Minutes
** Viruses		
Pathogen	Strain	Contact Time
Norovirus (as Feline Calicivirus)	ATCC VR-782	30 seconds
Poliovirus type 1	ATCC VR-1562, Strain Chat	1 Minute
Fungi		
Pathogen	Strain	Contact Time
Trichophyton interdigitate	ATCC 9533	5 Minutes

USE SITES [AREAS]:

For Use on Hard, Non-Porous Surfaces at the Following Medical Sites:	
Hospitals [including] [emergency rooms] [critical] [and] [intensive] [care] [units] [neonatal units] [isolation areas] [and] [quarantine rooms] [Ambulances] [Emergency Medical] [Transport vehicles] Ambulatory Surgical Centers (ASC) Anesthesia [Rooms] [Areas] [Assisted Living] [Full Care] Nursing Homes Carts CAT Lab[oratories] Central Service Areas Central Supply [Rooms] [Areas] Cleanrooms Compounding pharmacies [Critical Care Units] [CCUs]	Hospital Kitchens Hospices Hospitals [Intensive Care Units] [ICU[s]] Isolation Areas Laundry Rooms Laboratories Long Term Care Facilities [Medical] Clinics Medical Facilities [Medical] [Physician's] [Doctor's] Offices

Dialysis [Clinics] [Facilities] Doctors' Offices Donation Centers [blood] [plasma] [Emergency Rooms] [ERs] Eye Surgical Centers Health Care [Settings] [Facilities] Home Health Care [Settings]	[Newborn] [Neonatal] [Nurseries] [Intensive Care] Units [NICU] Nursing Homes [Nursing] [Nurses'] Stations Operating Rooms Ophthalmic Offices Orthopedics
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Out-Patient [Surgical] [Centers] [(OPSC)] [Clinics] [Facilities] [Nursing] [retirement] homes Operating rooms, patient rooms, Veterinary [clinics] [offices] [animal hospitals] [animal housing and grooming facilities] Pharmacies [Laboratories] [animal life science laboratories] Patient Areas Patient Restrooms Patient Rooms [Pediatric] Examination [Rooms] [Areas] Pediatric Intensive Care Units [PICU] Pharmacies	Physical Therapy [Rooms] [Areas] Dental Offices/Clinics Operating Theaters (OTs) Patient Waiting Ares Patient Rooms Physicians' Offices Psychiatric Facilities Public [Care] Areas [Radiology] [X-Ray] [Rooms] [Areas] Recovery Rooms Rehabilitation Centers Respiratory Therapy [Rooms] [Areas] Restrooms [Surgery] [Operating] [Rooms] [ORs] Waiting [Rooms] [Areas] recycled –or- [%x] recyclable plastic pH neutral Ready to use VOC compliant VOC free
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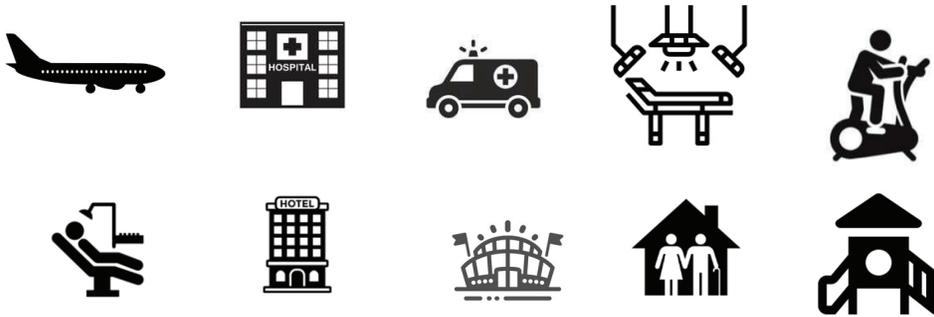
Veterinary Environments, Hard, Non-Porous Surfaces

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| <ul style="list-style-type: none"> • Amphibian [Holding] [Containment] Areas • Animal [Equine] Housing Facilities [Stables] • Animal Life Science Laboratories • Animal – or – Pet Grooming Facilities • Aquariums • [Raptor] Aviaries • [Chicken] [Bird] Coops • Falcon Housing Facilities • Feed Lots • [Animal] [Pet] Grooming [Facilities] [Kennels] • Animal Housing Facilities • Animal Life Science Laboratories • [Livestock] [Swine] [Poultry] [Equine] Facilities • Pet Areas • Pet Hotels – and/or – Motels • Pet [Shops] [Stores] • Small Animal Facilities • [Veterinary] [Animal] Hospitals • Veterinary [Clinics] [Facilities] • Veterinary Offices • [Petting] Zoos | <ul style="list-style-type: none"> • Animal Equipment Automatic Feeders • Aquariums • Cages • External Surfaces of Veterinary Equipment • Feed Racks • Fountains • Environmental Veterinary Surfaces • Pens • Pet Bowls [Areas] • Pet Feeding [Dishes] • [Pet] [Dog] [Cat] [Bird] [Animal] Toys • Reception [Counters] [Desks] [Areas] • Stables • Stalls • Troughs • Veterinary Care Surfaces • Watering Appliances |
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USE SURFACES:

[Ceramic] [Glazed] Tile Chrome Corian Formica Glass Linoleum Metal Non-Porous Plastic	Glazed Porcelain Sealed Granite Sealed Marble Marble Stainless Steel Vinyl [Finished] [Painted] Wood
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OPTIONAL GRAPHICS:



STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage or disposal.

Storage: Store this product in its original sealed container at room temperature, away from direct sunlight and heat. Do not allow product to freeze.

Pesticide Disposal: Pesticide wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available.